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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
09/990,773 11/14/2001 Kiamars Hajizadeh		Kiamars Hajizadeh	3873 P 011 1833	
75	90 07/19/2004		EXAM	INER
Wallenstein & Wagner, Ltd.			SWARTZ, RODNEY P	
53rd Floor 311 S. Wacker Drive			ART UNIT	PAPER NUMBER
Chicago, IL 60606-6622			1645	

DATE MAILED: 07/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary Raminer Rodney P. Swartz, Ph.D. R45		Application No.	Applicant(s)				
Rodney P. Swartz, Ph.D. 1645	Office of Acadients Occurrence of	09/990,773					
The MALING DATE of this communication appears on the cover sheet with the correspondence address — Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ③ MONTH(S) FROM THE MALING DATE OF THIS COMMUNICATION. Entendence for time may be available used the processors of 3 CFR 1.13(s), in no event, however, may a reply be timely filed If the period for reply specified above a level amailthy (SIO) alsys, an apply when the statutory minimum of tibely (30) days will be considered from the communication of the period for reply is application. If the period for reply is specified with the reply will be provided by the considered from the reply will be provided by the considered from the reply will be provided by the considered from the reply will be provided by the communication of the reply will be considered from the reply will be considered from the reply will be provided by the communication of the reply should be a selected from the reply will be considered from the reply will be reply and will be considered from the reply w	Office Action Summary	Examiner	Art Unit				
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1) Responsive to communication(s) filed on 17February2004. 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final. 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) ☐ Claim(s) 1-34 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) ☐ Claim(s) 1-34 is/are rejected. 7) ☐ Claim(s) 1-34 is/are rejected. 7) ☐ Claim(s) are subject to restriction and/or election requirement. Application Papers 9) ☐ The specification is objected to by the Examiner. 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) ☐ All b) ☐ Some * c) ☐ None of: 1. ☐ Certified copies of the priority documents have been received in Application No 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). *See the attached detailed Office action for a list of the certified copies not received. Attachment(s) 1) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) ☐ Holmation Disclosure Statement(s) (PTO-1449 or PTO/S800) 5) ☐ Notice of Informal Patent Application (PTO-152)	THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply 'received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any						
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DETAILED ACTION

- 1. Applicant's Response to Office Action, received 17February2004, is acknowledged.
- 2. Claims 1-34 are pending and under consideration.

Rejections Withdrawn

3. The rejection of claims 25-27 and 29-34 under 35 U.S.C. 112, second paragraph, as being indefinite for "a pair of antibodies specific to PrP^{sc}, is withdrawn in light of applicant's argument.

Rejections Maintained

4. The rejection of claims 1-24 and 28 under 35 U.S.C. 112, second paragraph, as being indefinite for "a pair of antibodies specific to PrPSC", is maintained for reasons of record.

Applicant argues that the language is quite clear that the present invention utilizes two different antibodies based upon language in the specification.

The examine has considered applicant's argument, but does not find it persuasive. While the specification may teach the embodiments contained in applicant's argument, the claims do not contain the criticalities of these embodiments. The claims do not limit the definition of "a pair of antibodies specific to PrPSC" to that which is in the specification. Thus, it remains indefinite if the claims are drawn solely to one antibody which is utilized two times or if two separate antibodies are being claimed.

Claim Rejections - 35 USC § 112

- 5. The following is a quotation of the first paragraph of 35 U.S.C. 112:
 - The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
- 6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 7. Claims 25-27, and 29-32 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: how one assays for only PrP^{SC} by using an immunochromatographic technique when there are no discriminating elements, e.g., antibodies specific to PrP^{SC} being utilized.
- 8. Claim 32 is rejected under 35 U.S.C. 112, second paragraph, insufficient antecedent basis, because the claim recites the limitation "The method of claim 25 wherein the labeled antibody has a colored lable.". Claim 25 does not recite "labeled antibody".

Conclusion

- 9. No claims are allowed.
- 10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

11. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private

PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RODNEY P SWARTZ, PH.D PRIMARY EXAMINER

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July 14, 2004